Nobody Can Be Forced To Get Vaccinated Rules Indian Supreme Court

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In a major judgement, the Supreme Court ruled on Monday that no one can be forced to get vaccinated, and that under Article 21 of the Constitution, an individual's right to bodily integrity includes the freedom to refuse vaccination.

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The Court also ruled that vaccine mandates enforced by state governments as well as other bodies in the wake of the COVID-19 pandemic are "not proportionate" The Court reached this conclusion because no sufficient evidence has been presented on the record to establish that the danger of COVID-19 virus transmission from unvaccinated individuals is greater than from vaccinated people.

The government has the authority to place restrictions on individual rights in the name of public health, but those constraints must satisfy the Supreme Court's three-part legality, genuine need, and proportionality test established out in the Puttaswamy decision.

"No data has been placed by the Union of India or the States appearing before us, controverting the material placed by the Petitioner in the form of emerging scientific opinion which appears to indicate that the risk of transmission of the virus

from unvaccinated individuals is almost on par with that from vaccinated persons. In light of this, restrictions on unvaccinated individuals imposed through various vaccine mandates by State Governments / Union Territories cannot be said to be proportionate", the Court stated.

#### Review vaccine mandates

As a result, the Court recommended that all authorities, including private institutions and educational institutions, reconsider the restrictions placed on unvaccinated people. The Court did clarify, however, that this directive is limited to the current COVID pandemic situation. It further stated that it does not apply to any other COVID-19 appropriate behavior directives issued by the authorities.

"Till the infection rate remains low and any new development or research finding emerges which provides due justification to impose reasonable and proportionate restrictions on the rights of unvaccinated individuals, we suggest that all authorities in this country, including private organisations and educational institutions, review the relevant orders and instructions imposing restrictions on unvaccinated individuals in terms of access to public places, services and resources, if not already recalled.

It is clarified that in the context of the rapidly-evolving situation presented by the COVID-19 pandemic, our suggestion to review the vaccine mandates imposed by States / Union Territories, is limited to the present situation alone and is not to be construed as interfering with the lawful exercise of power by

the executive to take suitable measures for prevention of infection and transmission of the virus".

Union's vaccine policy not unreasonable or arbitrary.

The Court also ruled that the Union Government's stance on COVID-19 vaccine is justified. It also stated that the vaccinations' clinical trial data had been released in compliance with the appropriate standards. The evidence presented by the Union of India refutes the assertion that emergency usage authorisation was obtained hastily.

Publish reports on Adverse Events

The Supreme Court further ordered the Union of India to disclose reports on Adverse Events Following Immunization (AEFI) from the general public and doctors on a publicly accessible basis without jeopardizing the privacy of those who are reporting the adverse reactions.

Vaccination for children approved

In the case of children's vaccines, the Court stated that it is impossible to second-guess experts' opinions, and that immunization follows international standards and practices.

"On paediatric vaccine, it is in tune with international standards. We direct the Union of India to make sure the key findings of the stages of trial already approved for children be made public at the earliest", the Court said.

Dr. Jacob Puliyel filed a PIL contesting the vaccine requirements and seeking publishing of the clinical study and

adverse effects of vaccination. A bench comprised of Justices L Nageswara Rao and BR Gavai issued the ruling.

The objections against the writ petition's maintainability were dismissed by the Court. Though the president has broad policy discretion, this does not preclude the courts from scrutinizing the policy to see if it is outside the boundaries of arbitrariness.

Relevant Quotes from the judgment

On bodily integrity – no individual can be forced to get vaccinated

"The upshot of the above discussion leads to the following conclusions:

Bodily integrity is protected under Article 21 of the Constitution of India and no individual can be forced to be vaccinated.

Personal autonomy of an individual involves the right of an individual to determine how they should live their own life, which consequently encompasses the right to refuse to undergo any medical treatment in the sphere of individual health.

Persons who are keen to not be vaccinated on account of personal beliefs or preferences, can avoid vaccination, without anyone physically compelling them to be vaccinated. However, if there is a likelihood of such individuals spreading the infection to other people or contributing to mutation of the virus or burdening of the public health infrastructure, thereby affecting communitarian health at large, protection of which is undoubtedly a legitimate State aim of paramount significance in

this collective battle against the pandemic, the Government can regulate such public health concerns by imposing certain limitations on individual rights that are reasonable and proportionate to the object sought to be fulfilled" -Paragraph 49.

Personal autonomy encompasses right to refuse undergo any medical treatment

"With respect to the infringement of bodily integrity and personal autonomy of an individual considered in the light of vaccines and other public health measures introduced to deal with the COVID-19 pandemic, we are of the opinion that bodily integrity is protected under Article 21 of the Constitution and no individual can be forced to be vaccinated.

Further, personal autonomy of an individual, which is a recognised facet of the protections guaranteed under Article 21, encompasses the right to refuse to undergo any medical treatment in the sphere of individual health" – Para 89(iii)

Vaccine mandates are not proportionate

"While there is abundant data to show that getting vaccinated continues to be the dominant expert advice even in the face of new variants, no submission nor any data has been put forth to justify restrictions only on unvaccinated individuals when emerging scientific evidence appears to indicate that the risk of transmission of the virus from unvaccinated individuals is almost on par with that from vaccinated persons.

To put it differently, neither the Union of India nor the State Governments have produced any material before this Court to justify the discriminatory treatment of unvaccinated individuals in public places by imposition of vaccine mandates. No doubt that when COVID-19 vaccines came into the picture, they were expected to address, and were indeed found to be successful in dealing with, the risk of infection from the variants in circulation at the time. However, with the virus mutating, we have seen more potent variants surface which have broken through the vaccination barrier to some extent.

While vaccination mandates in the era of prevalence of the variants prior to the Delta variant may have withstood constitutional scrutiny, in light of the data presented by the Petitioner, which has not beencontroverted by the Union of India as well as the State Governments, we are of the opinion that the restrictions on unvaccinated individuals imposed through vaccine mandates cannot be considered to be proportionate, especially since both vaccinated and unvaccinated individuals presently appear to be susceptible to transmission of the virus at similar levels"- Para 58

Authorities asked to review vaccine mandates

"No data has been placed by the Union of India or the States appearing before us, controverting the material placed by the Petitioner in the form of emerging scientific opinion which appears to indicate that the risk of transmission of the virus from unvaccinated individuals is almost on par with that from vaccinated persons. In light of this, restrictions on unvaccinated

individuals imposed through various vaccine mandates by State Governments / Union Territories cannot be said to be proportionate.

Till the infection rate remains low and any new development or research finding emerges which provides due justification to impose reasonable and proportionate restrictions on the rights of unvaccinated individuals, we suggest that all authorities in this country, including private organisations and educational institutions, review the relevant orders and instructions imposing restrictions on unvaccinated individuals in terms of access to public places, services and resources, if not already recalled.

It is clarified that in the context of the rapidly-evolving situation presented by the COVID-19 pandemic, our suggestion to review the vaccine mandates imposed by States / Union Territories, is limited to the present situation alone and is not to be construed as interfering with the lawful exercise of power by the executive to take suitable measures for prevention of infection and transmission of the virus. Our suggestion also does not extend to any other directions requiring maintenance of COVID-appropriate behaviour issued by the Union or the State Governments" – Para 89(v)

Union's vaccination policy reasonable

"On the basis of substantial material filed before this Court reflecting the near-unanimous views of experts on the benefits of vaccination in addressing severe disease from the infection, reduction in oxygen requirement, hospital and ICU admissions, mortality and stopping new variants from emerging, this Court is satisfied that the current vaccination policy of the Union of India is informed by relevant considerations and cannot be said to be unreasonable or manifestly arbitrary. Contrasting scientific opinion coming forth from certain quarters to the effect that natural immunity offers better protection against COVID-19 is not pertinent for determination of the issue before us" – Para 89(iii).

# Judicial review of policy decision

"As far as judicial review of policy decisions based on expert opinion is concerned, there is no doubt that wide latitude is provided to the executive in such matters and the Court does not have the expertise to appreciate and decide on merits of scientific issues on the basis of divergent medical opinion. However, this does not bar the Court from scrutinising whether the policy in question can be held to be beyond the pale of unreasonableness and manifest arbitrariness and to be in furtherance of the right to life of all persons, bearing in mind the material on record" – Para 89(ii).

## Background

Dr. Jacob Puliyel, a former member of the National Technical Advisory Group on Immunization, had filed a petition with the Supreme Court, questioning the constitutionality of vaccination mandates implemented by states, particularly Delhi, Madhya Pradesh, Maharashtra, and Tamil Nadu. He had asked the Court for permission to issue orders for the relevant authorities to reveal data from clinical studies of COVID-19 vaccinations

delivered to adults and children in India, as required by international medical standards. The petitioner also asked the Court to overhaul the Adverse Events Following Immunization Reporting System, which he claimed was opaque, flawed, and poorly understood by the general public.

Contentions raised by the petitioner

### Vaccine Mandates

Advocate Mr. Prashant Bhushan's main contention against vaccine requirements was that individuals were prevented from giving educated consent in the lack of clinical trial data, which infringed on the right to self-determination guaranteed by Article 21 of the Indian Constitution of 1950. He emphasized that informed consent is required for medical operations and that physical integrity is a fundamental aspect of the right to privacy, citing K Puttaswamy v. UOI (2017) 10 SCC 1 and Common Cause v. UOI (2018) 5 SCC1.

The Court was informed that, despite the fact that the Indian government has said that vaccines will be delivered on a voluntary basis, the States have enforced mandates limiting movement, denying basic services, and limiting the right to livelihood, in violation of Articles 19 and 21. Mr. Bhushan argued that mandating vaccination is unconstitutional when there is scientific evidence to support the claims that natural immunity is superior to vaccine immunity; vaccination does not prevent infection or transmission; vaccines are ineffective in preventing new variants; vaccines have serious side effects; and vaccine long-term consequences are unknown.

"For any vaccine to be mandated, the public health rationale underlying such a policy must be based essentially on efficacy and safety of vaccination and prevention of transmission of the disease", Mr. Bhushan submitted.

He cited the UK Parliamentary Committee's judgment, as well as the High Court of New Zealand's decision in Yardley v. Minister for Workplace Relations and Safety [2022] NZHC 291 and rulings from the Gujarat High Court and the Meghalaya High Court enforcing vaccine mandates.

### Non-Disclosure of data

Mr. Bhushan argued that the segregated data from vaccine clinical trials should be published in peer-reviewed scientific journals. The information would have a substantial influence on assessing the vaccinations' side effects. The Nuremberg Code and the Parliamentary Standing Committee on Health and Family Welfare's Reports Nos. 59 (2012) and 66 (2013) were used to argue for the importance of transparency.

He informed the Court that an RTI request had been submitted inquiring whether the Subject Expert Committee had reviewed and/or discussed the raw days. The Central Drugs Control Standard Organization responded by stating that the summary of interim clinical trial data as well as the recommendations of the Subject Expert Committee were publicly available on the CDSCO website. Displeased with the answer, an appeal was lodged, and the First Appellate Authority declined to provide any data, citing the manufacturers' refusal to publicly disclose data.

Adverse Effect Following Immunization Reporting System

Mr. Bhushan claimed that, in addition to having an opaque and defective system, there was a shortage of public awareness.

## Children's Vaccine Mandate

Mr. Bhushan claimed, citing scientific studies, that because the overall danger from COVID-19 for children is so minimal, it is not fair to vaccinate them, especially without giving parents the opportunity to provide informed permission.

Contentions raised by the respondents

#### **Union Government**

Mr. Tushar Mehta, the Solicitor General, had initially questioned the petitioner's credibility. He argued that the petitioner cannot request raw data from the COVID-19 vaccines clinical trial simply to satiate his curiosity, nor can he sit in judgment on domain experts' wisdom through a Public Interest Litigation. He denied the claim that there would be major side effects. According to the official record, 1,80,13,23,547 doses were delivered between March 13, 2012 and March 13, 2012, and 77314 individuals, or 0.004% of the immunized population, were adversely affected. In response to Mr. Bhushan's allegations of anomalies in the vaccine approval procedure, he walked the Court through the legislative framework and claimed that it had been followed when clearance was granted. He cited the Epidemic Diseases Act of 1897 and the Disaster Management Act of 2005 to highlight the broad range of

authority granted to the Central Government in the event of a pandemic.

Mr. Mehta fiercely refuted the petitioner's contention that there was no procedure in place to handle adverse vaccination effects. On the subject of clinical trial data dissemination, it was claimed that this went against confidentiality requirements. It was pointed out that the petitioner's reliance on the Helsinki Declaration and the WHO statement to obtain raw clinical trial data only applies to the responsibility to reveal final conclusions, findings, and outcomes that have already been released. When it came to the question of children's vaccine mandates, it was asserted that the petitioner's data was based on mRNA vaccines, while the vaccines used in India were neutralized virus vaccines. It was also mentioned that there is a statutory framework in place for pediatric immunizations, which is scrupulously adhered to.

Mr. Mehta cited a slew of international judgements on vaccination in general, and vaccination during the COVID-19 epidemic in particular, to show that individual liberty is not absolute and is influenced by other circumstances such as a valid goal and the need to attain that goal. Furthermore, he claimed that the vaccine requirement is a question of policy, not science, and that the scope of judicial review in policy matters is restricted, particularly when the executive decision is based on expert opinion.

State Governments

Tamil Nadu

Mr. Amit Anand Tiwari, appearing for the State of Tamil Nadu, argued that the State Government has used its powers under the Tamil Nadu Public Health Act, 1939, and the Disaster Management Act, 2005 to compel vaccination for entry to public spaces. The mandate was justified on the premises of three factors:

It prevents mutation

Unvaccinated people causes health risk and

Economic impact.

Maharashtra

Mr. Rahul Chitnis, appearing for the State of Maharashtra, argued that although the government has mandated vaccination for entry into shops, malls, and public transportation, the requirement would pass the proportionality test laid out by the Supreme Court in Modern Dental College And Research Centre And Ors. v. State of Madhya Pradesh.

## Madhya Pradesh

The Counsel agreed with the Solicitor General's assertions that rights must be balanced. It was also stated that the government had no intention of making vaccinations a condition of receiving rations. The goal of the notification, on the other hand, was to encourage people to get vaccinated.

## Vaccine Manufacturers

Mr. Guru Krishnakumar, a senior advocate for Bharat Biotech, refuted Mr. Bhushan's claim that the vaccine's Phase III Trial

had not been disclosed. Furthermore, it was emphasized that the petitioner's referenced WHO guidelines do not require the sharing of source data but only the analysis of the data. Section 8(1)(d) of the Right to Information Act was invoked, which exempts the revelation of information such as commercial confidence, trade secrets, or intellectual property that may undermine a third party's competitive position. The petitioner's request for disclosure was similarly denied by SII's counsel.

## Rebuttal Arguments of the petitioner

Mr. Bhushan claimed that the failure to release trial data prevents impartial experts from making their own decisions. He emphasized the petitioner's argument that disclosure would allow independent experts to examine the makers' claims for authenticity. He cited a United States District Court ruling in this regard, in which the regulatory agency was ordered to reveal all information about the Pfizer vaccine.

Even taking into account the government's stance on the privacy of the patients who participated in the studies, he argued that segregated data should have been made available. He emphasized that the government's claim that immunizations greatly reduce the risk of disease transmission must be supported by proof. Mr. Bhushan contended that just claiming that a robust system for giving permission existed does not exempt it from judicial scrutiny. Mr. Bhushan claimed that the information on the website solely applies to expert body recommendations and does not indicate the source on which such recommendations were based. In terms of the adverse

reporting system, he noted that only the vaccinee can record unpleasant effects; the general public is unaware of the system, and only known ill effects can be reported.

Read the full judgement below:

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